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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/518,599 | 05/31/2005 | Joseph M. Penninger | SONN:064US | 8087 |

32425 7590 01/03/2006
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EXAMINER

SINGH, ANOOP KUMAR

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/518,599 | PENNINGER ET AL. | |
| | Examiner | Art Unit | |
| | Anoop Singh | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-97 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 67-97 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 67-97 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 67-69, drawn to a method of treating an ACE2 decreased state comprising administering to a mammal effective amount of ACE2-agonist.

Group II, claims 67-69, drawn to a method of treating an ACE2 decreased state comprising administering to a mammal effective amount of ACE2-activator.

Group III, claims 67-72, drawn to a method of gene therapy for an ACE2-decreased state by delivering a transgene coding ACE2.

Group IV, claim 67-69 and 73, drawn to a method of treating ACE2 decreased state by administering a combination of ACE2 activator along with an ACE inhibitor.

Group V, claims 74-82, drawn to a polynucleotide comprising a sequence that binds to upstream or downstream of ACE2 nucleic acid coding region which is proximate to a nucleotide polymorphism that decreases ACE2 expression.

Group VI, claims 83-97, drawn to a method of ACE2 genotyping an animal comprising obtaining an ACE2 nucleic acid sample from the animal and detecting a region of an ACE2 nucleic acid that includes a SNP in the nucleic acid sample.

The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The technical feature linking the inventions of groups I-VI is method of treating ACE2 decreased state by ACE2 agonist. Acton et al., (WO 02/12471, publication date 2/14/02) disclose methods to administer either locally or systemically to a subject a pharmaceutically effective amount of a composition comprising an ACE-2 therapeutics. Acton et al do not limit the treatment to any specific condition. Acton et al describe that the therapeutics can be an ACE2 agonist or an antagonist. It is noted that Acton et al further describe that ACE agonist is administered locally to a subject to reduce the inflammation and pain resulting from the insect bite which was accompanied by an injection of bradykinin (pp 11, line 8-14).

Therefore, the instant technical feature of Groups I-VI does not contribute over prior art.

Additionally, The inventions of groups I-IV and VI are patentably distinct, each from other because they are drawn to methods that have distinct steps, mode of action, require separate composition for practice and produce different results. The method of group I requires treatment of ACE2 decrease state by ACE2 agonist, while group II requires an activator which is different from group III that requires nucleic acid coding ACE2 for gene therapy. In contrast, the invention of method group IV requires administering ACE2 activator along with ACE2 inhibitor which is different from method step of group VI that require obtaining ACE2 nucleic acid sample from the animal. The composition, mode of action and method step of each groups are distinct and different. Thus, searching for a method using different and distinct composition and different method steps will not be coextensive in the patent and non-patent literature.

The composition of the groups V is patentably distinct each from the methods of groups I-IV and VI because methods cannot be used to produce the compositions. Alternatively, the compositions may not be used in methods or will be used in more than one method.

Each invention is directed to distinct and different goal, which comprises the use of ACE2 agonist in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-VI do

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not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

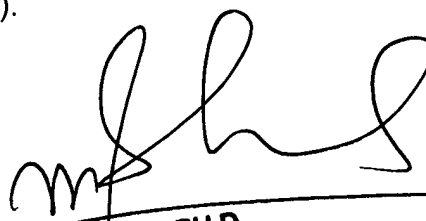
4. A search and examination of more than one invention as defined above would unduly burden the office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct method and compositions. Therefore, restriction as defined above is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272- 0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anoop Singh, Ph.D.
Examiner, AU 1632


RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER